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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/582,404      | 06/23/2000  | NOBORU YAMASHITA     | 19941A-00030        | 9067             |

7590 11/19/2003

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EXAMINER

PRYOR, ALTON NATHANIEL

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1616

DATE MAILED: 11/19/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/582,404

Applicant(s)

YAMASHITA ET AL.

Examiner

Alton N. Pryor

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☐ Claim(s) 4,6-10,12-15,17,18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 17 and 18 is/are allowed.
- 6) ☐ Claim(s) 4,6 and 7 is/are rejected.
- 7) ☐ Claim(s) 8-10 and 12-15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
- a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_.

*Claim Rejection under 35 U.S.C. 102(b)*

I. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 4,7 is rejected under 35 U.S.C. 102(b) as being anticipated by Hirano et al (Yakubutsu Dotai, 1989, vol. 4 no. pp. 779-92). Hirano teaches a compound of instant formula I where  $X = CH=CH$ ,  $R_5 = H$ ,  $R_7 = H$ ,  $E = OH$  and  $R_6 = C_3H_6C=C-Me$  (Beraprost sodium). Beraprost sodium is orally administered to dogs. Beraprost is then excreted in dog's urine. It is inherent that the composition excreted by dogs as urine would comprise ionic compounds. In a composition drawn to a composition, the components of the composition limit the claims, not a statement as to how the component is derived (synthetically).

*Claim Rejection under 35 U.S.C. 103(a)*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirano as applied to claims 4,7 above. See 35 U.S.C. 102(b) rejection above. Hirano teaches all that is recited in claim 6 except for equimolar amounts of ionic compound to ionic prostaglandin I2 derivatives. It would have been obvious to one having ordinary skill in the art to determine the optimum amounts of ingredients. One would have been motivated to do this in order to make a composition that would have properly function.

***Claim Objection / Allowable Subject Matter***

Claims 8-10,12-15 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach or suggest an anionic form of the prostaglandin I2 derivative of the formula I compound. The prior art does not teach or suggest the instant prostaglandin I2 derivative of claim 12. Claims 17 and 18 are allowable. The prior art does not teach the instant composition of claim 17 comprising an ionic prostanoic acid derivative plus an ionic compound having a carboxyl, sulfate, sulfonate or phosphate group in the molecule thereof or a salt thereof.

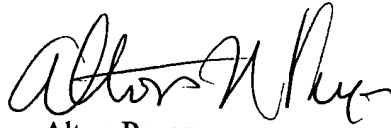
***Telephonic Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton Pryor whose telephone number is (703) 308-4691. The examiner can normally be reached on Monday through Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for this Group is (703) 308-4556.

Art Unit: 1616

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink, appearing to read 'Alton Pryor', with a stylized, cursive script.

Alton Pryor

Primary Examiner, AU 1616

11/16/03